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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,464	03/28/2001	Martin Friede	B45070-1	1150

7590 01/11/2005

GLAXOSMITHKLINE
Corporate Intellectual Property -UW2220
P. O. Box 1539
King of Prussia, PA 19406-0939

EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/819,464	Applicant(s) FRIEDE ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 30 November 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 47, 48 and 50-73.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____


Continuation of 2. NOTE: The new claims add further limitations that have not been examined such as the identification of a minimum requirement for the QS21 purity, the identification of metal salts other than alum salts, the limitation indicating that the compositions may further comprise any derivative of any enterobacterial liposaccharide, and the identification of specific antigens that may be included. Additionally, it is noted that the claim amendments have not been presented in a format conforming to the requirements of 37 CFR 1.121. There is no complete listing of all the claims, both cancelled and pending.

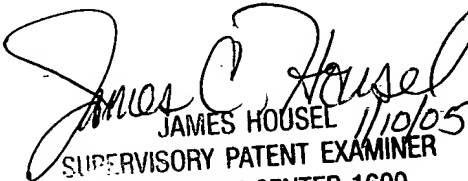
Continuation of 5. does NOT place the application in condition for allowance because: The Applicant has presented an additional argument as to why the combination of Kensil and Lipford would not, according to the Applicant, render the claimed inventions obvious. Applicant asserts that those in the art would not be motivated to substitute the purified QS21 in the place of the mixture Quil A. Applicant asserts that this is because "the essential characteristic of Quil A that allows it to form the ISCOM is its overall physico-chemical behaviour." While the Applicant purports to quote a sentence from Lipford supporting this assertion, the sentence merely states how the ISCOM was formed, and does not note any essential characteristic of Quil A for ISCOM formation.

It is noted that Lipford states (on page 78, second full paragraph) that there are two aspects of ISCOM important to their activity- the liposome structure and the adjuvant properties of Quil A. However, it is not clear that this would lead those in the art to expect that QS21 could not replace the Quil A mixture. For example, the teachings in Kensil (column 12, lines 21-30) indicate that the properties Lipford identified for Quil A are also indicative of adjuvant properties of saponins in general. Thus, Kensil suggests that the fractions of Quil A including QS21, would have these properties of Quil A. Thus, it seems that those in the art would have expected QS21 to share with Quil A whatever essential characteristic for ISCOM formation it may have. As the Applicant has provided no evidence that such a essential characteristic is lacking in QS21, or that those in the art would not have expected QS21 to act as a functional equivalent to Quil A, the Applicant's argument is not found persuasive. The rejection is therefore maintained.

The Additional rejections and objections which the Applicant attempted to address by claim amendment are also maintained in view of the non-entry of the amendments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES HOUSEL 11/10/05
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600